

# Decision Memo for Intensive Behavioral Therapy for Obesity (CAG-00423N)

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## Decision Summary

The Centers for Medicare and Medicaid Services (CMS) has determined the following:

The evidence is adequate to conclude that intensive behavioral therapy for obesity, defined as a body mass index (BMI)  $\geq 30$  kg/m<sup>2</sup>, is reasonable and necessary for the prevention or early detection of illness or disability and is appropriate for individuals entitled to benefits under Part A or enrolled under Part B and is recommended with a grade of A or B by the U.S. Preventive Services Task Force (USPSTF).

Intensive behavioral therapy for obesity consists of the following:

1. Screening for obesity in adults using measurement of BMI calculated by dividing weight in kilograms by the square of height in meters (expressed in kg/m<sup>2</sup>);
2. Dietary (nutritional) assessment; and
3. Intensive behavioral counseling and behavioral therapy to promote sustained weight loss through high intensity interventions on diet and exercise.

The intensive behavioral intervention for obesity should be consistent with the 5-A framework that has been highlighted by the USPSTF:

1. **Assess:** Ask about/assess behavioral health risk(s) and factors affecting choice of behavior change goals/methods.
2. **Advise:** Give clear, specific, and personalized behavior change advice, including information about personal health harms and benefits.
3. **Agree:** Collaboratively select appropriate treatment goals and methods based on the patient's interest in and willingness to change the behavior.

4. **Assist:** Using behavior change techniques (self-help and/or counseling), aid the patient in achieving agreed-upon goals by acquiring the skills, confidence, and social/environmental supports for behavior change, supplemented with adjunctive medical treatments when appropriate.
5. **Arrange:** Schedule follow-up contacts (in person or by telephone) to provide ongoing assistance/support and to adjust the treatment plan as needed, including referral to more intensive or specialized treatment.

For Medicare beneficiaries with obesity, who are competent and alert at the time that counseling is provided and whose counseling is furnished by a qualified primary care physician or other primary care practitioner and in a primary care setting, CMS covers:

- One face-to-face visit every week for the first month;
- One face-to-face visit every other week for months 2-6;
- One face-to-face visit every month for months 7-12, if the beneficiary meets the 3kg weight loss requirement as discussed below.

At the six month visit, a reassessment of obesity and a determination of the amount of weight loss must be performed. To be eligible for additional face-to-face visits occurring once a month for an additional six months, beneficiaries must have achieved a reduction in weight of at least 3kg over the course of the first six months of intensive therapy. This determination must be documented in the physician office records for applicable beneficiaries consistent with usual practice. For beneficiaries who do not achieve a weight loss of at least 3kg during the first six months of intensive therapy, a reassessment of their readiness to change and BMI is appropriate after an additional six month period.

For the purposes of this decision memorandum, a primary care setting is defined as one in which there is provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. Emergency departments, inpatient hospital settings, ambulatory surgical centers, independent diagnostic testing facilities, skilled nursing facilities, inpatient rehabilitation facilities and hospices are not considered primary care settings under this definition.

For the purposes of this decision memorandum a “primary care physician” and “primary care practitioner” will be defined consistent with existing sections of the Social Security Act (§1833(u)(6), §1833(x)(2)(A)(i)(I) and §1833(x)(2)(A)(i)(II)).

#### §1833(u)

(6) Physician Defined.—For purposes of this paragraph, the term “physician” means a physician described in section 1861(r)(1) and the term “primary care physician” means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

#### §1833(x)(2)(A)

Primary care practitioner—The term “primary care practitioner” means an individual—

(i) who—

(I) is a physician (as described in section 1861(r)(1)) who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; or

(II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1861(aa)(5)).

While this benefit is limited to primary care practitioners and primary care settings, it does not preclude primary care practitioners from screening beneficiaries for obesity and referring those who screen positive with a BMI  $\geq 30$  kg/m<sup>2</sup> to other practitioners and/or settings for intensive multicomponent counseling; however coverage remains only in the primary care setting.

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## Decision Memo

TO: Administrative File: CAG-00423N

FROM:

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SUBJECT: Final Coverage Decision Memorandum for Intensive Behavioral Therapy for  
Obesity

DATE: November 29, 2011

## **I. Decision**

The Centers for Medicare and Medicaid Services (CMS) has determined the following:

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## II. Background

The USPSTF recommendation for screening for obesity in adults (December 2003) states the following:

- The USPSTF recommends that clinicians screen all adult patients for obesity and offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults. **Grade: B Recommendation.**

The USPSTF explained this recommendation using the following rationale:

- “The USPSTF found good evidence that body mass index (BMI), calculated as weight in kilograms divided by height in meters squared, is reliable and valid for identifying adults at increased risk for mortality and morbidity due to overweight and obesity. There is fair to good evidence that high-intensity counseling—about diet, exercise, or both—together with behavioral interventions aimed at skill development, motivation, and support strategies produces modest, sustained weight loss (typically 3-5 kg for 1 year or more) in adults who are obese (as defined by BMI  $\geq 30$  kg/m<sup>2</sup>). Although the USPSTF did not find direct evidence that behavioral interventions lower mortality or morbidity from obesity, the USPSTF concluded that changes in intermediate outcomes, such as improved glucose metabolism, lipid levels, and blood pressure, from modest weight loss provide indirect evidence of health benefits. No evidence was found that addressed the harms of counseling and behavioral interventions. The USPSTF concluded that the benefits of screening and behavioral interventions outweigh potential harms.”

Over the years, obesity (generally accepted as defined as a body mass index (BMI)  $\geq 30$  kg/m<sup>2</sup>) and overweight (BMI 25-30 kg/m<sup>2</sup>) have become increasingly important disease risk factors not only in developed countries but now also worldwide. The Centers for Disease Control and Prevention (CDC) reported that “obesity rates in the U.S. have increased dramatically over the last 30 years, and obesity is now epidemic in the United States” (Kahn, 2009). For older adults (age  $\geq 60$  years), the prevalence of obesity is about 37% among men and 34% among women based upon recent data from the National Health and Nutrition Examination Survey (NHANES) (Flegal, 2010). Obesity is directly or indirectly associated with many chronic diseases including cardiovascular disease, musculoskeletal conditions and diabetes. In older adults, overweight and obesity were also found to be associated with “new or progressive ADL [activities of daily living] and IADL [instrumental activities of daily living] disability in a dose-dependent manner” (Wee 2011).

Given the increasing importance of obesity, CMS initiated a national coverage analysis (NCA) in March 2011 to assess the USPSTF Grade B recommendation for Screening for Obesity in Adults.



Since the 2003 recommendation, several studies have been published on obesity and reported consistent findings. For older adults (age  $\geq 60$  years), a systematic review conducted by McTigue and colleagues in 2006 reinforced these recommendations and stated that “intensive counseling can promote modest sustained weight loss.” In 2009, a systematic review by Brown and colleagues reported that “diet with exercise and/or behaviour therapy demonstrated significant reduction in hypertension and improvement in risk of metabolic syndrome and diabetes compared with no treatment control.” In 2011, a randomized controlled trial by Villareal and colleagues found that in obese older adults “a combination of weight loss and exercise provides greater improvement in physical function than either intervention alone.”

### **III. History of Medicare Coverage**

Pursuant to §1861(ddd) of the Social Security Act, CMS may add coverage of “additional preventive services” if certain statutory requirements are met. Our regulations provide:

#### **§410.64 Additional preventive services**

(a) Medicare Part B pays for additional preventive services not described in paragraph (1) or (3) of the definition of “preventive services” under §410.2, that identify medical conditions or risk factors for individuals if the Secretary determines through the national coverage determination process (as defined in section 1869(f)(1)(B) of the Act) that these services are all of the following:

- (1) Reasonable and necessary for the prevention or early detection of illness or disability.
- (2) Recommended with a grade of A or B by the United States Preventive Services Task Force.
- (3) Appropriate for individuals entitled to benefits under [P]art A or enrolled under Part B.

(b) In making determinations under paragraph (a) of this section regarding the coverage of a new preventive service, the Secretary may conduct an assessment of the relation between predicted outcomes and the expenditures for such services and may take into account the results of such an assessment in making such national coverage determinations.

#### **IV. Timeline of Recent Activities**

March 11, 2011	CMS initiates this national coverage analysis for Intensive Behavioral Therapy for Obesity, and the initial 30-day public comment period begins.
April 10, 2011	The initial 30-day public comment period closes.
August 31, 2011	The proposed decision memorandum is posted.
September 30, 2011	The second 30-day public comment period closes.

#### **V. Food and Drug Administration (FDA) Status**

Counseling services do not generally fall under the purview of the FDA.

#### **VI. General Methodological Principles**

When making national coverage determinations concerning additional preventive services, CMS applies the statutory criteria in §1861(ddd) of the Social Security Act and evaluates relevant clinical evidence to determine whether or not the service is reasonable and necessary for the prevention or early detection of illness or disability, is recommended with a grade of A or B by the USPSTF, and is appropriate for individuals entitled to benefits under Part A or enrolled under Part B of the Medicare program.

Public comments sometimes cite published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. Public comments that contain personal health information will not be made available to the public. CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum.

## VII. Evidence

### A. Introduction

Consistent with §1861(ddd)(1)(A) and 42 CFR 410.64(a)(1), additional preventive services must be reasonable and necessary for the prevention or early detection of illness or disability. With respect to evaluating whether screening tests conducted on asymptomatic individuals are reasonable and necessary, the analytic framework involves consideration of different factors compared to either diagnostic tests or therapeutic interventions. Evaluation of screening tests has been largely standardized in the medical and scientific communities, and the "value of a screening test may be assessed according to the following criteria:

- i. *Simplicity.* In many screening programmes more than one test is used to detect one disease, and in a multiphasic programme the individual will be subjected to a number of tests within a short space of time. It is therefore essential that the tests used should be easy to administer and should be capable of use by para-medical and other personnel.
- ii. *Acceptability.* As screening is in most instances voluntary and a high rate of co-operation is necessary in an efficient screening programme, it is important that tests should be acceptable to the subjects.
- iii. *Accuracy.* The test should give a true measurement of the attribute under investigation.
- iv. *Cost.* The expense of screening should be considered in relation to the benefits resulting from the early detection of disease, i.e., the severity of the disease, the advantages of treatment at an early stage and the probability of cure.

- v. *Precision (sometimes called repeatability)*. The test should give consistent results in repeated trials.
- vi. *Sensitivity*. This may be defined as the ability of the test to give a positive finding when the individual screened has the disease or abnormality under investigation.
- vii. *Specificity*. This may be defined as the ability of the test to give a negative finding when the individual screened does not have the disease or abnormality under investigation (Cochran and Holland 1971)."

As Cochrane and Holland (1971) further noted, evidence on health outcomes, i.e., "evidence that screening can alter the natural history of disease in a significant proportion of those screened," is important in the consideration of screening tests since individuals are asymptomatic and "the practitioner initiates screening procedures." The USPSTF has also integrated consideration of these factors in their assessments and recommendations.

## **B. United States Preventive Services Task Force (USPSTF)**

The USPSTF recommendation for screening for obesity in adults (December 2003) states the following:

- The USPSTF recommends that clinicians screen all adult patients for obesity and offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults. **Grade: B Recommendation.**

## **USPSTF Grade Definitions Prior to May 2007**

The U.S. Preventive Services Task Force (USPSTF) assigns one of five letter grades to each of its recommendations (A, B, C, D, I). The USPSTF changed its grade definitions based on a change in methods in May 2007).

The definitions below (of USPSTF grades and quality of evidence ratings) were in use prior to the update and apply to recommendations voted on by the USPSTF prior to May 2007.

**A – Strongly Recommended:** The USPSTF strongly recommends that clinicians provide [the service] to eligible patients. *The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.*

**B – Recommended:** The USPSTF recommends that clinicians provide [the service] to eligible patients. *The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.*

**C – No Recommendation:** The USPSTF makes no recommendation for or against routine provision of [the service]. *The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.*

**D – Not Recommended:** The USPSTF recommends against routinely providing [the service] to asymptomatic patients. *The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.*

**I – Insufficient Evidence to Make a Recommendation:** The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. *Evidence that the [service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined.*

## **C. Literature Search**

In addition to the prerequisite USPSTF recommendations, CMS must consider not only whether an additional preventive service is reasonable and necessary for the prevention or early detection of illness or disability, but whether the service is appropriate for individuals entitled to benefits under Part A or enrolled under Part B of the Medicare program.

To facilitate this determination, we searched PubMed from the year of the most recent evidence review and USPSTF recommendation to 2011 using key words: (1) obesity; (2) overweight; and (3) counseling for overweight and obesity. Given the extensive evidence base on this topic, randomized controlled trials and large prospective controlled studies were selected. Case reports and studies with methodologic issues such as limited generalizability to the Medicare population, short follow up time and high rate of participant disenrollment (loss to follow up) were excluded.

## **D. Discussion of Evidence Reviewed**

### **1. Questions:**

Our discussion focuses upon the adequacy of the evidence to draw conclusions about the risks and benefits of intensive behavioral counseling to promote sustained weight loss for obese Medicare beneficiaries. CMS analyzed the following questions:

- *Is the evidence sufficient to determine that screening for obesity in adults with intensive counseling and behavioral interventions to promote sustained weight loss for obese adults is recommended with a grade of A or B by the USPSTF?*

- Is the evidence sufficient to determine that screening for obesity in adults with intensive counseling and behavioral interventions to promote sustained weight loss for obese adults is reasonable and necessary for the prevention or early detection of illness or disability?

- Is the evidence sufficient to determine that screening for obesity in adults with intensive counseling and behavioral interventions to promote sustained weight loss for obese adults is appropriate for Medicare beneficiaries?

## 2. External technology assessment

*Brown T, Avenell A, Edmunds LD, Moore H, Whittaker V, Avery L, Summerbell C, for the PROGRESS Team. Systematic review of long-term lifestyle interventions to prevent weight gain and morbidity in adults. Obesity Reviews 2009;10:627–638.*

Brown and colleagues reported the results of a systematic review “to determine the effectiveness of interventions that focus on improving diet and activity behaviours in adults who are of normal weight, overweight and obese, to prevent weight gain and morbidity in the long-term.” Randomized controlled trials and controlled before and after studies on diet, exercise, and behavior in adults age 18–65 years with BMI <35 kg/m<sup>2</sup> with follow up of at least two years were included. Thirty-nine trials and one before/after study were reviewed. The authors reported that “eleven of 39 comparisons produced significant improvement in weight between groups at 2 years or longer with mean difference weight change ranging from -0.5 to -11.5 kg.” They concluded that “diet with exercise and/or behaviour therapy demonstrated significant reduction in hypertension and improvement in risk of metabolic syndrome and diabetes compared with no treatment control.”

*Curioni C, André C, Veras R. Weight reduction for primary prevention of stroke in adults with overweight or obesity. Cochrane Database of Systematic Reviews 2006, Issue 4. Art. No.: CD006062. DOI: 10.1002/14651858.CD006062.pub2.*

Curioni and colleagues reported the results of a systematic review “to assess the effects of weight reduction for primary prevention of stroke in adults with overweight and obesity.” The Cochrane database and Medline were searched for randomized controlled trials that compared any intervention for weight reduction with placebo or no intervention with a follow up period of at least one year. No suitable trials were located. The authors noted that “there are insufficient data to make recommendations for practice about the effects of weight reduction in people with overweight or obesity on stroke incidence.” They reported: “Overweight and obesity seem to be associated with an increased risk of stroke and it has been suggested that weight loss may lead to a reduction of stroke occurrence. However, this hypothesis is not based on strong scientific evidence from randomised controlled clinical trials.”

*Franz MJ, VanWormer JJ, Crain AL, Boucher JL, Histon T, Caplan W, Bowman JD, Pronk NP. Weight-loss outcomes: a systematic review and meta-analysis of weight-loss clinical trials with a minimum 1-year follow-up. J Am Diet Assoc 2007;107:1755-1767.*



Franz and colleagues reported the results of a systematic review “to determine types of weight-loss interventions that contribute to successful outcomes and to define expected weight-loss outcomes from such interventions.” Randomized controlled trials on overweight or obese adults with at least one year of follow up were included. Primary outcome of interest was weight loss. Eighty studies with 26,455 individuals were included. Interventions included diet, exercise and medications. Mean age at baseline ranged from 23 to 68 years. Mean BMI at baseline ranged from 29 to 40 kg/m<sup>2</sup>. The authors reported “interventions that include food and meal planning strategies—diet alone, diet and exercise, and meal replacements—resulted in a mean weight loss of approximately 5 to 8.5 kg (5% to 9%) from starting weight during the first 6 months. Weight-loss plateaus at approximately 6 months and stabilized to a weight loss of approximately 4.5 to 7.5 kg (4.8% to 8%) at 12 months. Weight loss of approximately 3 to 4 kg (3% to 4.3%) was maintained at 24, 36, and 48 months with none of the groups experiencing weight regain to baseline. Numerous reports have concluded that this amount of weight loss contributes to important health benefits.”

*Leblanc ES, O'Connor E, Whitlock EP, Patnode CD, Kapka T. Effectiveness of primary care-relevant treatments for obesity in adults: a systematic evidence review for the U.S. Preventive services task force. Ann Intern Med 2011;155:434-47.*

LeBlanc and colleagues reported the results of a systematic review “to summarize effectiveness and harms of primary care–relevant weight-loss interventions for overweight and obese adults” and to assist the USPSTF in their update of the 2003 recommendations. They addressed four key questions:

1. “Is there direct evidence that primary care screening programs for adult obesity or overweight improve health outcomes or result in short-term (12 to 18 mo) or sustained (>18 mo) weight loss or improved physiologic measures (i.e., glucose tolerance, blood pressure, and dyslipidemia)?
  - a) How well is weight loss maintained after an intervention is completed?”
2. “Do primary care–relevant interventions (behaviorally based interventions and/or pharmacotherapy) in obese or overweight adults lead to improved health outcomes (morbidity from diabetes mellitus, cardiovascular disease, cancer, arthritis, asthma, sleep apnea, depression, emotional functioning, physical fitness capacity or performance, physical functioning, disability, mortality)?
  - a) What are common elements of efficacious interventions?
  - b) Are there differences in efficacy between patient subgroups (i.e., age 65 y or older, sex, race/ethnicity, degree of obesity, baseline cardiovascular risk)?”

3. “Do primary care–relevant interventions in obese or overweight adults lead to short-term or sustained weight loss, with or without improved physiologic measures?
  - a) How well is weight loss maintained after an intervention is completed?
  - b) What are common elements of efficacious interventions?
  - c) Are there differences in efficacy between patient subgroups (i.e., age 65 y or older, sex, race/ethnicity, degree of obesity, baseline cardiovascular risk)?”
4. “What are the adverse effects of primary care–relevant interventions in obese or overweight adults (e.g., nutritional deficits, cardiovascular disease, bone mass loss, injuries, death)?
  - a) Are there differences in adverse effects between patient subgroups (i.e., age 65 y or older, sex, race/ethnicity, degree of obesity, baseline cardiovascular risk status)?”

The investigators reviewed 6498 abstracts and included 648 articles in the analysis. Inclusion criteria included controlled trials of weight loss interventions for adults in primary care settings. Exclusion criteria were based on general categories of relevance, setting, population, outcomes, interventions, design, quality and study period. Outcomes included mortality, cardiovascular disease, hospitalization, diabetes, and weight loss. Interventions included “physical activity sessions, group sessions, individual sessions, technology-based intervention, specific weight-loss goals, spouse or family involvement, addressing barriers to weight loss, motivational assessment (for example, pros and cons of weight loss), self-monitoring, incentives, or support after active intervention phase.”

The authors reported: “Behaviorally based treatment resulted in 3-kg (6.6-lb) greater weight loss in intervention than control participants after 12 to 18 months, with more treatment sessions associated with greater loss. Limited data suggest weight-loss maintenance for 1 year or more. Orlistat plus behavioral intervention resulted in 3-kg (6.6-lb) more weight loss than did placebo after 12 months. Metformin resulted in less weight loss. Data on effects of weight-loss treatment on long-term health outcomes (for example, death and cardiovascular disease) were insufficient. Weight-loss treatment reduced diabetes incidence in participants with prediabetes. Effects on intermediate outcomes (for example, lipids and blood pressure) were mixed and small. Data on serious medication harms were insufficient. Medications commonly caused withdrawals due to gastrointestinal symptoms.” They concluded: “Behaviorally based treatments are safe and effective for weight loss and maintenance.”

*McTigue KM, Hess R, Ziouras J. Obesity in Older Adults: A Systematic Review of the Evidence for Diagnosis and Treatment. Obesity 2006;14:1485-1497.*

McTigue and colleagues reported the results of a systematic review “to better understand obesity-related health risk and the potential for interventions to alter such risk.” They addressed four key questions regarding obesity in older adults: “Is obesity associated with long-term health risks? Can obesity be diagnosed with anthropometric measures? Can intervention result in weight loss? Can weight loss result in improved health outcomes?” Studies with average age  $\geq 60$  years were included. Studies with follow-up of less than one year were excluded. The authors reported:

1. “Obese older adults are at increased risk for incident cardiovascular risk factors and events, certain cancers, and impaired mobility but are somewhat protected from hip fracture and lung cancer.”
2. “In older adults, obesity can be diagnosed easily and inexpensively using anthropometric measures. Although the correlation between BMI and fat mass is lower in older adults than in the general population, the difference is typically small.”
3. “In older adults, intensive counseling-based interventions incorporating diet and exercise can lead to modest (3 to 4 kg) sustained weight loss.”
4. “This loss is sufficient to show a clinical improvement in glucose control and a reduction in the combined incidence of blood pressure abnormalities and cardiovascular events. Intervention results in a similar amount of weight loss in younger adults, but this amount appears to be more beneficial in preventing or delaying the onset of diabetes in older individuals. Modest weight loss may improve overall physical functioning in older adults with lower extremity arthritis.”

They concluded: “Relatively healthy older adults who are at increased risk for cardiovascular disorders or arthritis-related functional impairment are likely to benefit from diagnosis of obesity and initiation of intensive lifestyle interventions. Intensive interventions that include diet, physical activity, and behavioral components are most likely to promote health. Dietary components should reflect evidence-based approaches for weight loss while emphasizing the importance of nutrition, because malnutrition is common in the elderly and sometimes difficult to detect. Physical activity should be tailored to accommodate chronic disease, sensory deficits, or functional limitations. In older adults at high risk for osteoporosis, any consideration of intentional weight loss must carefully balance the potential benefits and harms and should incorporate physical activity to minimize bone loss.”

*McTigue K, Harris R, Hemphill MB, Bunton AJ, Lux LJ, Sutton S, Lohr KN. Screening and Interventions for Obesity in Adults: Summary of the Evidence for the U.S. Preventive Services Task Force. Ann Intern Med 2003;139:933-949.*

McTigue and colleagues reported the results of a systematic review “to determine the effectiveness of adult obesity screening—the conscious measurement of weight status to clinically address body weight—and treatment.” The authors preferred evidence from randomized, controlled trials or systematic reviews of randomized controlled trials. The authors found:

1. “Obesity is a risk factor for major causes of death, including cardiovascular disease, numerous types of cancer, and diabetes, and is linked with markedly diminished life expectancy. Osteoarthritis, gall bladder disease, sleep apnea, respiratory impairment, diminished mobility, and social stigmatization are associated with obesity.”
2. “Body mass index, the most common screening test for obesity, is easy to measure, highly reliable, and closely correlated ( $r = 0.7$  to  $0.8$ ) with adult body fat. Validity may vary by demographic characteristics, including ethnicity and possibly age. Clinical relevance is established by prospective links with diverse health outcomes.”
3. “Although RCT evidence for long-term improved health with weight loss is limited, weight loss—associated changes in intermediate health variables suggest benefit. In the setting of escalating obesity prevalence, the importance of considering body weight in clinical practice seems clear. With counseling, obese patients can achieve modest but clinically significant, sustained (1 to 2 years) weight loss (for example, 3 to 5 kg). Because control groups also frequently received some intervention, this estimate may be conservative. More intense programs were generally more successful, as were those incorporating behavioral therapy.”
4. “We found less evidence for effects of weight loss on ultimate (generally symptomatic) health outcomes. Limited observational data suggest that intentional weight loss in obese persons (particularly those with comorbid conditions) can reduce mortality. Two large RCTs showed that behaviorally mediated weight loss can prevent diabetes among those with glucose intolerance (58% reduction;  $P < 0.05$ ) (67, 81). A smaller reduction in diabetes incidence (31% [CI, 17% to 43%]) was seen among similar metformin-treated patients.”

The authors concluded: “Counseling and pharmacotherapy can promote modest sustained weight loss, improving clinical outcomes. Pharmacotherapy appears safe in the short term; long-term safety has not been as strongly established. In selected patients, surgery promotes large amounts of weight loss with rare but sometimes severe complications.”

### 3. Internal technology assessment

*Mozaffarian D, Hao T, Rimm EB, Willett WC, Hu FB. Changes in Diet and Lifestyle and Long-Term Weight Gain in Women and Men. N Engl J Med 2011;364:2392-2404.*

Mozaffarian and colleagues reported the results of a combined analysis to investigate “the relationship between multiple lifestyle changes, both independently and jointly, and long-term weight gain in nonobese women and men participating in three separate, prospective studies.” The authors pooled data from the Nurses’ Health Study (NHS), a prospective cohort of 121,701 female registered nurses, the Nurses’ Health Study II (NHS II), a prospective cohort of 116,686 younger female registered nurses, and the Health Professionals Follow-up Study (HPFS), a prospective cohort of 51,529 male health professionals. Individuals with obesity, diabetes, cancer, or cardiovascular, pulmonary, renal, or liver disease at baseline and those who were over 65 years of age were among the excluded. Mean ages at baseline were 52 years, 38 years and 51 years, respectively.

The authors noted that potato chips, potatoes, sugar-sweetened beverages, unprocessed red meats and processed meats were most strongly associated with 4 year weight change (gain) and that intake of vegetables, whole grains, fruits, nuts and yogurt were inversely associated.

They concluded: “A habitual energy imbalance of about 50 to 100 kcal per day may be sufficient to cause the gradual weight gain seen in most persons. This means that unintended weight gain occurs easily but also that modest, sustained changes in lifestyle could mitigate or reverse such an energy imbalance. Our findings suggest that both individual and population-based strategies to help people consume fewer calories may be most effective when particular foods and beverages are targeted for decreased (or increased) consumption. Aggregate dietary changes accounted for substantial differences in weight gain, with additional contributions from changes in physical activity and television watching, thus highlighting specific lifestyle changes that might be prioritized in obesity prevention strategies.”

*Park Y, Subar AF, Hollenbeck A, Schatzkin A. Dietary Fiber Intake and Mortality in the NIH-AARP Diet and Health Study. Arch Intern Med 2011;171:1061-1068.*

Park and colleagues reported the results of an analysis of the Diet and Health Study, a large cohort study by the National Institutes of Health (NIH) and the American Association of Retired Persons (AARP). A baseline dietary questionnaire was sent to 3.5 million AARP members in six states in 1995 and 1996. Of these 617,119 men and women responded (17.6%). For this analysis, 388,122 (219,123 men and 168,999 women) were included. Cox hazard models were used in the analyses. Mean age at baseline was about 62 years. Mean follow up was nine years. The authors reported that “dietary fiber intake was associated with a significantly lowered risk of total death in both men and women (multivariate relative risk comparing the highest with the lowest quintile, 0.78 [95% CI, 0.73-0.82; P for trend, < .001] in men and 0.78 [95% CI, 0.73-0.85; P for trend, < .001] in women).”

The authors stated: “In conclusion, our study shows that dietary fiber may reduce the risk of premature death from all causes, especially from CVD and infectious and respiratory diseases. The current Dietary Guidelines for Americans recommend choosing fiber-rich fruits, vegetables, and whole grains frequently and consuming 14 g/1000 calories of dietary fiber. A diet rich in dietary fiber from whole plant foods may provide significant health benefits.”

*Shea MK, Houston DK, Nicklas BJ, Messier SP, Davis CC, Miller ME, Harris TB, Kitzman DW, Kennedy K, Kritchevsky SB. The effect of randomization to weight loss on total mortality in older overweight and obese adults: the ADAPT Study. J Gerontol A Biol Sci Med Sci 2010;65:519-525.*

Shea and colleagues reported the results of an analysis of data from the Arthritis, Diet, and Activity Promotion Trial (ADAPT) to “determine whether randomization to a weight reduction program was associated with total mortality in overweight/obese older adults.” ADAPT, which ended in 1999, was a “single-blind randomized controlled intervention trial designed to determine whether dietary weight loss and long-term exercise training, alone or in combination, could improve physical function and mobility and reduce pain in overweight and obese (mean baseline body mass index [BMI] 34 kg/m<sup>2</sup>) men and women aged 60 years and older with knee OA [osteoarthritis].” In the initial study, 316 individuals were included in the analysis. Baseline mean age was about 68 years. Women comprised about 71% of the study population. For this analysis, 318 individuals were included based on an intention to treat approach. Deaths were determined using the Social Security Index (SSI) and the National Death Index (NDI) through 2006. Mean follow-up time was eight years. The authors reported that “mortality rate for those randomized to the 18-month weight loss intervention (n = 159, mean weight loss = -4.8 kg, 15 deaths) was lower than that for those not randomized to the weight loss intervention (n = 159, mean weight loss = -1.4 kg, 30 deaths; hazard rate ratio = 0.5, 95% confidence interval 0.3–1.0).” They concluded that “in older adults, intentional weight loss was not associated with increased total mortality and may reduce mortality risk.”

*Sui X, LaMonte MJ, Laditka JN, Hardin JW, Chase N, Hooker SP, Blair SN. Cardiorespiratory Fitness and Adiposity as Mortality Predictors in Older Adults. JAMA 2007; 298: 2507–2516.*

Sui and colleagues reported the results of a prospective cohort study to evaluate “associations among cardiorespiratory fitness, adiposity [obesity], and mortality in older adults.” Adults age 60 years and older were enrolled from 1979 to 2001 at one site (Cooper Clinic in Texas). Of the 2603 enrolled, 80% were men. Mean age was 64 years. Mean follow-up was 12 years. The authors found that death rates increased with BMI (“Death rates per 1000 person-years, adjusted for age, gender, and examination year were: 13.9, 13.3, 18.3, and 31.8 across BMI groups of 18.5-24.9, 25.0-29.9, 30.0-34.9, and ≥ 35 kg/m<sup>2</sup>, respectively (trend P = .01)”).

The authors stated: “In conclusion, our prospective findings in adults ages 60 and over show that low fitness predicted higher all-cause mortality risk after adjustment for potential confounding factors including adiposity. Fit individuals had greater longevity than unfit individuals regardless of their body composition or fat distribution. Our data provide further evidence regarding the complex long-term relationship among fitness, body size, and survival. We may be able to reduce all-cause death rates among older adults, including those who are obese, by promoting regular physical activity, such as brisk walking for 30 minutes or more on most days of the week (about 8-kcal/kg per week), which will keep most individuals out of the low fitness category. Enhancing functional capacity also should allow older adults to achieve a healthy lifestyle and to enjoy longer life in better health.”

*Villareal DT, Chode S, Parimi N, Sinacore DR, Hilton T, Armamento-Villareal R, Napoli N, Qualls C, Shah K. Weight Loss, Exercise, or Both and Physical Function in Obese Older Adults. N Engl J Med 2011;364:1218-1229.*

Villareal and colleagues reported the results of a randomized, controlled trial “to determine the independent and combined effects of sustained weight loss and regular exercise on physical function, body composition, and quality of life in obese older adults.” Individuals age 65 years and older with a BMI  $\geq 30$  kg/m<sup>2</sup> with sedentary lifestyles and stable weight and medications were included. Exclusion criteria were “severe cardiopulmonary disease; musculoskeletal or neuromuscular impairments that preclude exercise training; visual, hearing, or cognitive impairments; or a history of cancer, as well as persons who were receiving drugs that affect bone health and metabolism or who were current smokers.” Primary outcome was the change from baseline in performance testing including standing, walking and climbing. Interventions occurred weekly and included dietary assessment, dietary counseling and exercise training. A total of 107 individuals were randomized to three intervention groups (diet, exercise, diet and exercise) or one control group. Mean age was about 70 years. Men comprised about 37% of the population. Of the 107, 93 participants completed the 12 month trial.

The authors reported that physical performance increased significantly in all three intervention groups compared to control. The increase was greatest in the diet and exercise group. They concluded: “that weight loss alone or exercise alone improves physical function and ameliorates frailty in obese older adults; however, a combination of weight loss and regular exercise may provide greater improvement in physical function and amelioration of frailty than either intervention alone.”



#### 4. Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) Meeting

CMS did not hold a MEDCAC meeting on this topic.

#### 5. Evidence-based Clinical Guidelines

*Dahn JR, Fitzpatrick SL, Llabre MM, Apterbach GS, Helms RL, Cugnetto ML, Klaus J, Florez H, Lawler T. Weight management for veterans: examining change in weight before and after MOVE! Obesity (Silver Spring) 2011;19:977-981.*

Dahn and colleagues reported the results of a study “to assess treatment effects of MOVE! Weight Management Program for Veterans by comparing the trajectory of change in weight postintervention (3, 6, and 12 months postenrollment) to a preintervention period (1, 3, and 5 years before enrollment).” Based upon on the National Institutes of Health (NIH) guidelines and the 2003 USPSTF recommendation, the MOVE! (Managing Overweight/Obesity for Veterans Everywhere; [www.move.va.gov](http://www.move.va.gov)) program was designed “to offer an evidence-based, multidisciplinary, comprehensive approach to weight management that is centered around the patient and tailored to individual needs.” At one site (VA Miami, FL), 862 veterans who had a BMI  $\geq 30.0$  kg/m<sup>2</sup> or a BMI of 25.0-30.0 kg/m<sup>2</sup> with one or more obesity-related conditions, such as diabetes, hypertension and participated in the program. All veterans “participated in a 2-h Self-Management Support (SMS) session, which involved completion of a self-assessment questionnaire and a nutrition education group session.” After this, “veterans had the option of continuing with Supportive Group Sessions (SGS), which included 10-weekly group sessions led by a multidisciplinary team.” Mean age was about 54 years. Men comprised about 86% of the population. Follow-up duration was 12 months. The authors reported that “weight for participants in SMS stabilized after enrollment whereas participants in SGS had an average weight loss of 1.6 kg/year.” They concluded that “findings from this study support the need for a lifestyle modification program such as MOVE! in primary care settings to assist overweight and obese patients in managing their weight.”

Kinsinger LS, Jones KR, Kahwati L, Harvey R, Burdick M, Zele V, Yevich SJ. Design and dissemination of the MOVE! weight-management program for veterans. *Prev Chronic Dis* 2009;6(3). [http://www.cdc.gov/pcd/issues/2009/jul/08\\_0150.htm](http://www.cdc.gov/pcd/issues/2009/jul/08_0150.htm).

Kinsinger and colleagues reported the design and implementation plan of MOVE! The program was “created on the basis of guidelines from the National Institutes of Health (NIH) and other current literature.” The program followed the 2003 US Preventive Services Task Force recommendation that “clinicians screen all adult patients for obesity and offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults.” “Designed to be integrated into patients’ ongoing care and implemented in primary care clinics, MOVE! is a clinical process and set of tools for facilities and clinicians to offer an evidence-based, multidisciplinary, comprehensive approach to weight management that is centered around the patient and tailored to individual needs.”

The components of MOVE! include: (1) “a paper or Web-based 23-item baseline assessment, the MOVE!23 questionnaire ([www.move.va.gov/Move23.asp](http://www.move.va.gov/Move23.asp)). This assessment elicits information about medical history; weight and weight-management history; motivational factors; barriers to modifying physical activity, diet, and weight-related behaviors and patients’ readiness to change these behaviors. On completion, patients receive a summary report that identifies their individual needs and recommendations, supplemented by tailored links to specific patient handouts.” (2) staff assisted patient specific “short term nutrition, physical activity, or behavior change goals. Staff provide diet and physical activity logs and may give pedometers to patients to track steps. Staff follow up with patients by telephone or in person in 1 to 3 weeks to determine progress toward or barriers to meeting goals. Ideally, staff-patient contact is ongoing, based on continuing patient need and desire for supported self-management. Many patients also attend group sessions for further instruction and support.” (3) “Modules for multidisciplinary staff to use in conducting group sessions ([www.move.va.gov/GrpSessions.asp](http://www.move.va.gov/GrpSessions.asp)) have been developed as part of MOVE!. Individual consultation is available for patients who need tailored treatment plans because of comorbid illness or other complicating factors. For patients who need more intensive interventions, Veterans Affairs (VA) facilities provide on a limited basis weight-loss medications, intensive medical management, and bariatric surgery.”

Lin JS, O’Connor E, Whitlock EP, Beil TL. Behavioral Counseling to Promote Physical Activity and a Healthful Diet to Prevent Cardiovascular Disease in Adults: A Systematic Review for the U.S. Preventive Services Task Force. *Ann Intern Med* 2010;153:736-750.

Lin and colleagues reported the results of a systematic evidence review to “assist the U.S. Preventive Services Task Force in updating its previous recommendations by systematically reviewing trials of physical activity or dietary counseling to prevent cardiovascular disease.” They addressed the following key questions: (1) “Do primary care-relevant behavioral counseling interventions for physical activity or healthful diet improve cardiovascular disease health outcomes (prevent morbidity and mortality) in adults?” (2) “Do primary care-relevant behavioral counseling interventions for physical activity or healthful diet improve intermediate outcomes associated with cardiovascular disease (such as lipid levels, blood pressure, glucose tolerance, weight, or body mass index) in adults (including older adults)?” (3) “Do primary care-relevant behavioral counseling interventions for physical activity or healthful diet change associated health behaviors in adults?” (4) “What are the adverse effects of primary care-relevant behavioral counseling interventions for physical activity or healthful diet in adults?”

Trials on primary care–relevant counseling on physical activity or healthful diet interventions were included. Studies with “interventions primarily aimed at weight loss or those that provided controlled diets or supervised physical activity” were excluded. Of the 481 studies reviewed, 66 were included in the analysis. Of these, 13 were considered good quality trials. Intervention intensity was categorized as “low [ $\leq 30$  minutes], medium [between 31 minutes and 6 hours of contact], or high [ $> 6$  hours of contact].” Men accounted for approximately 17% of all trial participants. Eleven trials included only women. Weighted mean age was 59 years. There were nine trials in older adults. The authors reported: “Long-term observational follow-up of intensive sodium reduction counseling showed a decrease in the incidence of cardiovascular disease; however, other direct evidence for reduction in disease morbidity is lacking. High-intensity dietary counseling, with or without physical activity counseling, resulted in changes of  $-0.3$  to  $-0.7$  kg/m<sup>2</sup> in body mass index (adiposity),  $-1.5$  mm Hg (95% CI,  $-0.9$  to  $-2.1$  mm Hg) in systolic blood pressure,  $-0.7$  mm Hg (CI,  $-0.6$  to  $-0.9$  mm Hg) in diastolic pressure,  $-0.17$  mmol/L (CI,  $-0.09$  to  $-0.25$  mmol/L) ( $-6.56$  mg/dL [CI,  $-3.47$  to  $-9.65$  mg/dL]) in total cholesterol level, and  $-0.13$  mmol/L (CI,  $-0.06$  to  $-0.21$  mmol/L) ( $-5.02$  mg/dL [CI,  $-2.32$  to  $-8.11$  mg/dL]) in low-density lipoprotein cholesterol level. Medium- and high-intensity counseling resulted in moderate to large changes in self-reported dietary and physical activity behaviors.” They concluded: “Counseling to improve diet or increase physical activity changed health behaviors and was associated with small improvements in adiposity, blood pressure, and lipid levels.”

*National Institute for Health and Clinical Excellence. Obesity guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children. NICE 2006;clinical guideline 43:1-84. At <http://www.nice.org.uk/nicemedia/live/11000/30365/30365.pdf>*

The National Institute for Health and Clinical Excellence (NICE) published evidence-based guidelines to help individuals “prevent and manage overweight and obesity.” They noted that “body mass index (BMI) should be used as a measure of overweight in adults.” They classified individuals with a BMI of 25-29.9 kg/m<sup>2</sup> as being overweight and individuals with a BMI ≥ 30 kg/m<sup>2</sup> as having obesity (I, II, III). They presented a number of lifestyle interventions approaches to assist with weight loss.

*U.S. DHHS, National Institutes of Health, National Heart, Lung, and Blood Institute National, High Blood Pressure Education Program. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. NIH Publication No. 04-5230 August 2004.*

The NIH highlighted the importance of diet: “Adoption of healthy lifestyles by all persons is critical for the prevention of high BP and is an indispensable part of the management of those with hypertension. Weight loss of as little as 10 lbs (4.5 kg) reduces BP and/or prevents hypertension in a large proportion of overweight persons, although the ideal is to maintain normal body weight. BP is also benefited by adoption of the Dietary Approaches to Stop Hypertension (DASH) eating plan which is a diet rich in fruits, vegetables, and low fat dairy products with a reduced content of dietary cholesterol as well as saturated and total fat (modification of whole diet). It is rich in potassium and calcium content. Dietary sodium should be reduced to no more than 100 mmol per day (2.4 g of sodium). Everyone who is able should engage in regular aerobic physical activity such as brisk walking at least 30 minutes per day most days of the week. Alcohol intake should be limited to no more than 1 oz (30 mL) of ethanol, the equivalent of two drinks per day in most men and no more than 0.5 oz of ethanol (one drink) per day in women and lighter weight persons. A drink is 12 oz of beer, 5 oz of wine, and 1.5 oz of 80-proof liquor. Lifestyle modifications reduce BP, prevent or delay the incidence of hypertension, enhance antihypertensive drug efficacy, and decrease cardiovascular risk. For example, in some individuals, a 1,600 mg sodium DASH eating plan has BP effects similar to single drug therapy. Combinations of two (or more) lifestyle modifications can achieve even better results. For overall cardiovascular risk reduction, patients should be strongly counseled to quit smoking.”

## **E. Public Comments**

During the initial 30-day public comment period (03/11/2011 – 04/10/2011) CMS received 27 public comments. Twenty five of these comments were generally supportive of coverage for intensive behavioral therapy for obesity. One commenter suggested that outstanding issues required attention before a determination could be made and one commenter provided comments that appeared to be unsupportive of Medicare coverage. While commenters largely agreed that intensive behavioral therapy for obesity should be provided at high intensity (once per week or once every two weeks), they also offered varying suggestions regarding appropriate components and providers of therapy services. Numerous commenters provided citations for publications to support their comments. CMS reviewed the referenced literature and included some in this analysis.

CMS received seven comments from education and advocacy associations; five from providers; four from professional societies; three from individuals who did not identify an associated organization or profession; two from weight loss organizations; and one each from a trade association, research society, pharmaceutical company, electronic-health company, academic institution, and health scientist.

The comments can be viewed in their entirety on our website at:

<http://www.cms.gov/medicare-coverage-database/details/nca-view-public-comments.aspx?NCAId=253&ExpandComments=n&ver=1&NcaName=Intensive+Behavioral+Therapy+for+Obesity&bc=ACAAAAAAIAAA&>.

### **Public Comment Period 08/31/2011 – 09/30/2011**

During the 30 day comment period on the proposed decision, CMS received 254 comments. The comments were overwhelmingly supportive of coverage for intensive behavioral therapy for obesity as this decision would be an important step in moving forward in the treatment of obesity. However, numerous commenters expressed concerns about and suggested revisions specific to various aspects of the proposed decision. Five commenters were not supportive of the proposed decision, citing a lack of evidence supporting intentional weight loss in seniors, a lack of long term methods for weight loss and claiming that that such a policy would be wasteful of limited Medicare resources.

## ***Practitioners***

### Comment

We received about 195 comments requesting that psychologists be included in the list of practitioners eligible to provide and receive reimbursement for intensive behavioral counseling for obesity. Eighty four commenters supported this request by noting that psychologists are trained to provide obesity counseling and in fact have the most extensive training in behavioral interventions. Seventy seven commenters further noted that psychologists have contributed the majority of the evidence base supporting the use of behavioral interventions for obesity.

Commenters also identified a variety of other practitioners they believed should be included in the list of practitioners eligible to furnish and receive reimbursement for intensive behavioral counseling for obesity. Specifically, 31 commenters requested the inclusion of registered dietitians and dietitians; 16 requested the inclusion of mental/behavioral health providers and specialists; six requested the inclusion of nutritionists; five requested the inclusion of social workers; four requested the inclusion of pharmacists; four requested the inclusion of exercise specialists; four requested the inclusion of exercise physiologists; three requested the inclusion of diabetes nurse educators; three requested the inclusion of certified obesity medical physicians; two requested the inclusion of counselors; two requested the inclusion of nurses; and two requested the inclusion of board certified behavioral analysts.

Inclusion of the following practitioners was supported by one commenter for each discipline: certified health coaches, exercise therapists, exercise scientists, preventive medicine specialists, athletic trainers, appropriately certified personal trainers, kinesiologists, sports medicine physicians, academically prepared professionals with specialized experience in obesity, occupational therapists, bariatric surgeons, bariatricians, obesity medicine specialists, bariatric medicine specialists, trained non-clinical providers, lay providers, peer health educators, PhDs, surgeons, physicians, cardiologists, commercial weight loss programs, RNs under the “incident to” policy, referral to lifestyle modification/integrated weight loss programs, primary care physician referrals to registered dietitians, and primary care physician referrals to psychologists, others with specialized experience, other allied health professionals, and other disciplines,

Commenters offered various reasoning to support inclusion of some of these practitioners. One commenter argued that the USPSTF recommendation is based on evidence in which registered dietitians were a part of the team or sole provider of therapy. One commenter noted that the inclusion of Assess and Arrange from the 5-A Framework requires the inclusion of registered dietitians as providers of these services. One commenter asserted that the sports medicine professional community has the knowledge, skills and abilities to deliver safe and effective programs including physical activity and nutrition prescription. Another commenter argued that research shows that high intensity interventions can be effective when offered by lay providers.

One commenter suggested that CMS develop a certification program to identify intensive behavioral therapy for obesity practitioners that offer the USPSTF elements. One commenter requested that CMS define what primary care clinicians are qualified to provide intensive behavioral therapy for obesity. Numerous commenters also stated that primary care physicians do not have the necessary training and therefore should not provide intensive behavioral therapy for obesity and thus other practitioners, such as psychologists and others identified above, should be covered.

## Response

*While CMS is providing coverage for additional preventive services, we believe it is important that these preventive services should be furnished in a coordinated approach as part of a comprehensive prevention plan within the context of the patient's total health care. Primary care practitioners are characterized by their coordination of a patient's comprehensive healthcare needs. Primary care practitioners are generalists who are specifically trained to provide primary care services. Other provider specialties may provide patient care in other settings but do not offer care in the context of being the coordinator of the patient's healthcare needs, not limited by problem origin or diagnosis. Coordination of health services is especially important in the presence of the coexisting health issues of our Medicare beneficiaries.*

*This decision covers intensive behavioral therapy for obesity when furnished in primary care settings, as described in section I. In the primary care office setting, Medicare may cover these services when billed by the primary care physician or practitioner and furnished by auxiliary personnel under the conditions specified under our regulation at 42 CFR section 410.26(b) (conditions for services and supplies incident to a physician's professional service). In the primary care hospital outpatient setting, Medicare may cover these services when furnished and billed by the primary care physician or practitioner as described in section I. In addition, Medicare may cover these services when furnished by the hospital, in outpatient hospital settings, under the conditions specified under our regulation at 42 CFR section 410.27 (conditions for outpatient hospital services and supplies incident to a physician service). We believe that providing for coverage under these conditions will permit appropriate staff to furnish intensive behavioral therapy for obesity while ensuring that services are delivered within the primary care setting in order to provide a coordinated approach as part of each patient's comprehensive prevention plan.*

## **Settings**

## **Comments**



Sixty three commenters requested that behavioral services not be limited to the primary care setting. Two commenters requested that covered settings be expanded to cover community-based settings. One commenter argued that fitness centers should be included as covered settings. One commenter specified that intensive behavioral therapy for obesity should be covered in the following settings: outpatient hospital, skilled nursing facilities, inpatient rehabilitation facilities, and independent and community based facilities. One commenter requested that the policy address coverage in skilled nursing facilities, specifically the number of caregivers needed to provide services. One commenter noted that the proposed decision does not allow for intensive behavioral therapy for obesity to be covered in hospital outpatient settings and that the final decision must be modified so that hospital based primary care clinics are not excluded from coverage. Two commenters requested that digital health coaching programs furnished through the internet be covered under this policy. One commenter requested that CMS provide more information on what settings are considered primary care settings.

### Response

*The USPSTF recommendations are for primary care settings; thus we proposed to exclude certain settings as falling outside primary care. Our proposed decision stated that emergency departments, inpatient hospital settings, outpatient hospital settings, ambulatory surgical centers, independent diagnostic testing facilities, skilled nursing facilities, inpatient rehabilitation facilities and hospices are not considered primary care settings.*

*A primary care setting is one where patients' care services are delivered by primary care specialists who serve as the coordinator of all patients' medical and health care needs, not limited by problem origin or diagnosis. Primary care specialists are characterized by being responsible for coordinating the care the patient receives from the entire health system. Other provider specialties may provide patient care in other settings but do not offer care in the context of being the coordinator of all the patient's healthcare needs. We agree that much primary care is delivered in hospital outpatient settings, such as hospital outpatient clinics. Patients in a skilled nursing facility were not studied in the evidence review, and the care delivered in this setting is more similar to an inpatient hospital setting than ambulatory care. As such, for the final decision, "skilled nursing facilities" has remained in the list of excluded settings and "outpatient hospital settings" has been removed.*

### **Components**

## Comments

Three commenters requested that in addition to BMI, waist circumference should be measured. These commenters also suggested including glucose risk scores, blood pressure and cholesterol. One commenter recommended including an assessment of physical activity. One commenter suggested that the goals of intensive behavioral therapy for obesity should be expanded to include weight maintenance and prevention of weight gain. This commenter also requested that patients who are overweight or at a healthy weight but experienced gradual weight gain throughout adulthood should be covered. One commenter requested that overweight patients with co-morbidities be covered. One commenter requested that CMS specify the types of treatments covered and that they should be evidence based.

## Response

*While we understand the desire for including more elements into these services, CMS believes that the decision as written incorporates the elements identified in the USPSTF recommendation. Specifically, the USPSTF recommendation is based on “good evidence that body mass index (BMI), calculated as weight in kilograms divided by height in meters squared, is reliable and valid for identifying adults at increased risk for mortality and morbidity...” The rationale does not incorporate the use of waist circumference, glucose risk scores, blood pressure or cholesterol.*

*The recommendation itself is specific to obesity and does not incorporate screening and therapy for overweight individuals or individuals who have experienced gradual weight gain throughout adulthood. In fact, the USPSTF found “that the evidence is insufficient to recommend for or against the use of counseling of any intensity and behavioral interventions to promote sustained weight loss in overweight adults.” This recommendation regarding overweight adults was assigned an I by the USPSTF and pursuant to §1861(ddd) of the Social Security Act, CMS may add coverage of “additional preventive services” if certain statutory requirements are met including an A or B recommendation by the USPSTF. As a result, this policy does not apply to patients who have a BMI under 30 kg/m<sup>2</sup>.*

*We appreciate the request to specify the treatments covered under this policy, however, more detailed descriptions of covered services would limit practitioners’ ability to customize treatment strategies for each patient. The policy as written allows for flexibility in providing individualized treatments within the framework of the coverage policy.*

### Comment

One commenter requested that the duration of intensive behavioral therapy for obesity should be at least one year and one commenter requests that it be expanded beyond one year. One commenter suggested incorporating long term services to allow patients who are making progress to continue receiving therapy. One commenter stated that he is unaware of evidence supporting the proposed schedule and that CMS should cover intensive behavioral therapy for obesity that is evidence based for this patient population. One commenter requested that the initial frequency period for counseling be extended to 10-12 weeks and one commenter requested that the number of counseling sessions be increased as the USPSTF recommendations call for a minimum of six sessions within 12 months.

### Response

*We believe that the frequency of sessions and duration of services is appropriate given the USPSTF recommendations. These aspects of the policy are consistent with the recommendations and rationale.*

### Comment

One commenter requested that services continue for patients who do not meet the six month weight loss requirement of 3kg, and argued that these patients need more help. One commenter stated that he supports the decision but is hesitant to support the “arbitrary” 3kg weight loss requirement. One commenter requested that no minimum weight loss be required for continued therapy.

### Response

*We believe it is important to establish weight loss requirements in order to ensure that patients are actually benefitting. While evidence reviewed in this analysis and by the USPSTF did not identify a specific weight loss expectation over a specific period of time, average weight loss over average periods of time were identified in systematic reviews between 3 and 8kg over six to twelve months. Weight loss of 3kg over six months is within these averages. The requirement also assists practitioners in evaluating patients’ readiness to change, as discussed in section VIII of this document.*

Comment

One commenter requested that evidence-based, group-based counseling be included.

Response

*Evidence-based, group-based counseling could be eligible for coverage if provided within the parameters of this policy.*

Comment

One commenter requested that specific obesity screening codes be established.

Response

*CMS is in the process of establishing codes. They will be part of the claims processing instructions for this NCD.*

Comment

One commenter suggested that CMS consider newer interventions such as web based for coverage.

Response

*Web based interventions fall outside the scope of this NCD.*

Comment

One commenter requested that restrictions be removed from the policy.

### Response

*We believe that any portions of the policy viewed as restrictions are necessary to ensure these services are provided to the appropriate patients under appropriate circumstances.*

### Comment

One commenter argued that pharmacotherapy should be included in the policy.

### Response

*Pharmacotherapy was not reviewed and is considered beyond the scope of this analysis. While the USPSTF noted in their 2011 draft update that “interventions that combine pharmacologic agents (orlistat or metformin) with behavioral interventions resulted in weight loss and improvement in physiologic outcomes,” they were “unable to recommend medication use” due to “concerns about the possible harms” and “a lack of sufficient data regarding the maintenance of improvement after discontinuation of medications.”*

## **Pediatric and Medicaid Patients**

### Comment

One commenter stated that the weight loss requirement should be modified for pediatric patients. One commenter requested that the definition of BMI be expanded to include the standard of practice for children. One commenter requested that a pediatric obesity criterion be included in this policy. Three commenters requested that intensive behavioral therapy for obesity be covered by Medicaid for children and younger individuals and families.

### Response

*Because this analysis examined the USPSTF recommendation for adults, this policy does not incorporate requirements specific to pediatric patients. Medicaid and its provisions fall outside of the scope of the NCD process and will not be discussed further.*

## **Miscellaneous**

### Comment

One commenter requested that CMS confer with the Agency for Healthcare Research and Quality (AHRQ) regarding the anticipated updated USPSTF recommendations before releasing a final decision.

### Response

*CMS is aware of and will stay informed regarding the progress of the recommendation final updates.*

### Comment

Three commenters recommended including references in the NCD to other treatment options for obese beneficiaries such as medication and surgery.

### Response

*Pharmacotherapy and bariatric surgery were not reviewed and are considered beyond the scope of this analysis. As discussed above, while the USPSTF noted in their 2011 draft update that “interventions that combine pharmacologic agents (orlistat or metformin) with behavioral interventions resulted in weight loss and improvement in physiologic outcomes,” they were “unable to recommend medication use” due to “concerns about the possible harms” and “a lack of sufficient data regarding the maintenance of improvement after discontinuation of medications.” The USPSTF (2011) did not comment on bariatric surgery. There are a number of existing Medicare NCDs with respect to obesity. Information on other options such as surgery may be found in the Medicare National Coverage Determinations Manual <https://www.cms.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS014961> or various other sections of the CMS website (<https://www.cms.gov/>).*

Comment

One commenter suggested that CMS educate practitioners and beneficiaries about this new benefit in order to ensure high utilization.

Response

*In addition to claims processing instructions, CMS will also release a Medicare Learning Network Matters article to communicate and promote the new policy and benefit.*

Comment

One commenter requested that CMS review and update this policy periodically.

Response

*We plan to follow this topic and such future USPSTF actions that may affect it.*

Comment

One commenter stated that CMS should not require intensive behavioral therapy as a pre-requisite for beneficiaries seeking bariatric surgery.

Response

*The policy does not include such a requirement and this issue falls outside the scope of this NCD.*

Comment

One commenter argued that CMS should defer the final decision until a full review of the updated USPSTF recommendation, clinical evidence and effective private plan/employer coverage policy is completed.

Response

*We disagree. NCDs, by statute, are expected to be finalized in a timely manner.*

Comment

One commenter argued that the proposed decision does not follow the USPSTF or clinical research of the last decade and one commenter requested that coverage more closely mirror the USPSTF recommendations.

Response

*We believe that this policy is consistent with both the USPSTF recommendation and available clinical evidence.*

Commenters submitted 102 citations and 32 web page links. Of the 102, 92 were published prior to 2011 and would have been included in the 2011 systematic review performed for the USPSTF by LeBlanc and colleagues. The 10 articles published in 2011 did not meet inclusion criteria since they were either commentaries (4), dealt with issues outside the scope of this review such as costs, time burden, and attitudes (4) or contained methodologic issues such as limited generalizability or significant loss of follow-up that made interpretation of the results difficult (2).

The references identified in the public comments are listed in Appendix A.

## **VIII. Analysis**



National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act §1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Since January 1, 2009, CMS is authorized to cover "additional preventive services" (see Section III above) if certain statutory requirements are met as provided under §1861(ddd) of the Social Security Act. Our regulations at 42 CFR 410.64 provide:

(a) Medicare Part B pays for additional preventive services not described in paragraph (1) or (3) of the definition of "preventive services" under §410.2, that identify medical conditions or risk factors for individuals if the Secretary determines through the national coverage determination process (as defined in section 1869(f)(1)(B) of the Act) that these services are all of the following:

- (1) Reasonable and necessary for the prevention or early detection of illness or disability.
- (2) Recommended with a grade of A or B by the United States Preventive Services Task Force.
- (3) Appropriate for individuals entitled to benefits under [P]art A or enrolled under Part B.

(b) In making determinations under paragraph (a) of this section regarding the coverage of a new preventive service, the Secretary may conduct an assessment of the relation between predicted outcomes and the expenditures for such services and may take into account the results of such an assessment in making such national coverage determinations.

*Is the evidence sufficient to determine that screening for obesity in adults with intensive counseling and behavioral interventions to promote sustained weight loss for obese adults is recommended with a grade of A or B by the USPSTF?*

In 2003 the USPSTF "recommends that clinicians screen all adult patients for obesity and offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults. Grade: B Recommendation."

Rationale: “The USPSTF found good evidence that body mass index (BMI), calculated as weight in kilograms divided by height in meters squared, is reliable and valid for identifying adults at increased risk for mortality and morbidity due to overweight and obesity. There is fair to good evidence that high-intensity counseling—about diet, exercise, or both—together with behavioral interventions aimed at skill development, motivation, and support strategies produces modest, sustained weight loss (typically 3-5 kg for 1 year or more) in adults who are obese (as defined by BMI  $\geq 30$  kg/m<sup>2</sup>). Although the USPSTF did not find direct evidence that behavioral interventions lower mortality or morbidity from obesity, the USPSTF concluded that changes in intermediate outcomes, such as improved glucose metabolism, lipid levels, and blood pressure, from modest weight loss provide indirect evidence of health benefits. No evidence was found that addressed the harms of counseling and behavioral interventions. The USPSTF concluded that the benefits of screening and behavioral interventions outweigh potential harms.”

In 2011, the USPSTF updated its review and issued a draft revision: “The U.S. Preventive Services Task Force (USPSTF) recommends that clinicians screen adults for obesity. Clinicians should offer or refer patients with a body mass index (BMI) greater than 30 kg/m<sup>2</sup> to intensive, multicomponent behavioral interventions (B recommendation).” The draft recommendation further notes: “The USPSTF found that weight loss programs improved weight loss outcomes when interventions involved a greater number of sessions (12 to 26 sessions in the first year). Behavioral intervention participants lost an average 6 percent of their baseline weight (4 to 7 kg [8.8 to 15.4 lb]) in the first year with 12 to 26 treatment sessions compared with little or no weight loss in the control group. Five percent weight loss is considered clinically important by the U.S. Food and Drug Administration (FDA).”

“Most of the higher-intensity behavioral interventions included behavioral management activities such as setting weight loss goals, improving diet/nutrition and increasing physical activity, addressing barriers to change, self-monitoring, and strategizing how to maintain lifestyle changes.”

“For obese patients with elevated plasma glucose, behavioral interventions decreased the incidence of diabetes diagnosis by about half over 2 to 3 years (number needed to treat [NNT] = 7.) Behavioral interventions also demonstrated some improvement in intermediate health outcomes such as blood pressure, waist circumference, and glucose tolerance.

Interventions that combine pharmacologic agents (orlistat or metformin) with behavioral interventions resulted in weight loss and improvement in physiologic outcomes. On average, orlistat led to an average weight loss of about 2.6 kg (5.7 lb), a 1.9 cm reduction in waist circumference, and a decrease in fasting glucose level.” However, due to various issues surrounding the use of pharmacotherapy for weight loss, the USPSTF was unable to make a general recommendation regarding medication use.

We conclude that screening for obesity in adults is recommended with a grade of A or B by the USPSTF.

*Is the evidence sufficient to determine that screening for obesity in adults with intensive counseling and behavioral interventions to promote sustained weight loss for obese adults is reasonable and necessary for the prevention or early detection of illness or disability?*

Obesity (defined as a BMI  $\geq 30$  kg/m<sup>2</sup>) has been identified as a “risk factor for major causes of death, including cardiovascular disease, numerous cancers, and diabetes, and is linked with markedly diminished life expectancy” (USPSTF, 2003). BMI is “the measure used to define obesity and is also the most commonly used test to screen for obesity” (USPSTF, 2003). The USPSTF also noted that “the BMI is easy to measure, highly reliable, and highly correlated with percentage of body fat and body fat mass ( $R^2 = 0.95$  in men;  $R^2 = 0.98$  in women).”

While a valid and reliable screening tool is important, proven interventions are then needed to improve health outcomes. After screening, nutritional assessment to aid in developing an intervention plan was of benefit. Past randomized controlled trials have shown that high intensity interventions (at least twice per month) can lead to long term weight loss. Extensive evidence exists on the indirect benefits of weight loss. Interventions included counseling on diet and exercise and behavioral therapy such as the 5-A method and other behavioral modification approaches. McTigue and colleagues (2003) reported that “counseling interventions produced modest (generally 3 to 5 kg) weight loss over at least 6 or 12 months, respectively.” They also noted that “counseling was most effective when intensive and combined with behavioral therapy” and that the modest “weight reduction improved blood pressure, lipid levels, and glucose metabolism and decreased diabetes incidence.” LeBlanc and colleagues (2011) reported that “behaviorally based treatment resulted in 3-kg (6.6-lb) greater weight loss in intervention than control participants after 12 to 18 months, with more treatment sessions associated with greater loss.” They also reported: “Interventions with more sessions showed more weight loss—patients receiving 12 to 26 intervention sessions generally lost 4 to 7 kg (8.8 to 15.4 lb) (6% of baseline weight) compared with 1.5 to 4 kg (3.3 to 8.8 lb) (2.8% of baseline weight) in intervention groups with fewer than 12 sessions in the first year.” Programs such as MOVE! developed by the Veterans Health Administration have assisted in translating evidence into clinical practice with demonstrated improvements. In addition, Shea and colleagues conducted a long term analysis (eight year average follow up) of a trial on dietary weight loss and long-term exercise training (ADAPT) in older adults and found that “intentional weight loss was not associated with increased total mortality and may reduce mortality risk.”

We conclude that the evidence is sufficient to determine that screening for obesity in adults along with high intensity behavioral interventions is reasonable and necessary for the prevention or early detection of illness or disability.

*Is the evidence sufficient to determine that screening for obesity in adults with intensive counseling and behavioral interventions to promote sustained weight loss for obese adults is appropriate for Medicare beneficiaries?*

As in the general population, the prevalence of obesity in older adults is increasing. While the evidence base for older adults is not as extensive, obesity can be detected and proven interventions exist. The USPSTF noted that “estimates of body fat percentages measured using BMI in the elderly have shown error rates comparable to those measured using BMI in younger adults (approximately 4 percent)” and that the “clinical relevance, or external validity, of BMI measurement is clear from the established prospective links between BMI and multiple adverse health outcomes.” McTigue and colleagues published results of a systematic review specifically for older adults. The authors identified several randomized controlled trials conducted in adults age 60 and older. They reported “in older adults, intensive counseling-based interventions incorporating diet and exercise can lead to modest (3 to 4 kg) sustained weight loss.” In a recently published trial, Villareal and colleagues found “that weight loss alone or exercise alone improves physical function and ameliorates frailty in obese older adults; however, a combination of weight loss and regular exercise may provide greater improvement in physical function and amelioration of frailty than either intervention alone.” LeBlanc and colleagues conducted a systematic review on weight loss in adults (age  $\geq 18$  years) and concluded that “behaviorally based treatments are safe and effective for weight loss and maintenance.” They reported: “Interventions with more sessions showed more weight loss—patients receiving 12 to 26 intervention sessions generally lost 4 to 7 kg (8.8 to 15.4 lb) (6% of baseline weight) compared with 1.5 to 4 kg (3.3 to 8.8 lb) (2.8% of baseline weight) in intervention groups with fewer than 12 sessions in the first year.” While exercise training (physical activity) has not yet received an USPSTF grade A or B, it is an extremely important component in weight loss programs. The USPSTF did state:

- “Regular physical activity helps prevent cardiovascular disease, hypertension, type 2 diabetes, obesity, and osteoporosis. It may also decrease all-cause morbidity and lengthen life-span.”
- “Benefits of physical activity are seen at even modest levels of activity, such as walking or bicycling 30 minutes per day on most days of the week. Benefits increase with increasing levels of activity.”

While this decision also does not address pharmacotherapy or surgery for obesity, physicians could consider adjunct therapy to maximize individual weight loss when medically necessary and indicated in a multicomponent approach and on an individual basis. We note this because these issues are addressed in the past recommendations and in the current draft recommendations.

We conclude that the evidence is sufficient to determine that screening for obesity in older adults along with high intensity behavioral interventions is appropriate for Medicare beneficiaries.

## Visit

### 1. Screening for Obesity

Obesity is defined as a body mass index (BMI)  $\geq 30$  kg/m<sup>2</sup>.

*Calculation of BMI (directly from the CDC at*  
[http://www.cdc.gov/healthyweight/assessing/bmi/adult\\_bmi/index.html](http://www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/index.html)

BMI is calculated the same way for both adults and children. The calculation is based on the following formulas:

Measurement Units	Formula and Calculation
<b>Kilograms and meters (or centimeters)</b>	<p>Formula: <math>\text{weight (kg)} / [\text{height (m)}]^2</math></p> <p>With the metric system, the formula for BMI is weight in kilograms divided by height in meters squared. Since height is commonly measured in centimeters, divide height in centimeters by 100 to obtain height in meters.</p> <p>Example: Weight = 68 kg, Height = 165 cm (1.65 m) Calculation: <math>68 \div (1.65)^2 = 24.98</math></p>
<b>Pounds and inches</b>	<p>Formula: <math>\text{weight (lb)} / [\text{height (in)}]^2 \times 703</math></p> <p>Calculate BMI by dividing weight in pounds (lbs) by height in inches (in) squared and multiplying by a conversion factor of 703.</p>

Measurement Units	Formula and Calculation
	Example: Weight = 150 lbs, Height = 5'5" (65") Calculation: $[150 \div (65)^2] \times 703 = 24.96$

### *Interpretation of BMI for Adults*

For adults 20 years old and older, BMI is interpreted using standard weight status categories that are the same for all ages and for both men and women. For children and teens, on the other hand, the interpretation of BMI is both age- and sex-specific. For more information about interpretation for children and teens, visit Child and Teen BMI Calculator (<http://apps.nccd.cdc.gov/dnpabmi/>).

The standard weight status categories associated with BMI ranges for adults are shown in the following table.

BMI	Weight Status
Below 18.5	Underweight
18.5 – 24.9	Normal
25.0 – 29.9	Overweight
30.0 and Above	Obese

For example, here are the weight ranges, the corresponding BMI ranges, and the weight status categories for a sample height.

Height	Weight Range	BMI	Weight Status
5' 9"	124 lbs or less	Below 18.5	Underweight
	125 lbs to 168 lbs	18.5 to 24.9	Normal
	169 lbs to 202 lbs	25.0 to 29.9	Overweight
	203 lbs or more	30 or higher	Obese

## 2. Nutritional Assessment

Ammerman and colleagues (for the USPSTF/AHRQ, 2002) reported:

“Several brief screening instruments have been developed to assess nutritional status in the elderly. Although many are designed for long-term-care patients, some have been validated in community-living elderly and are intended for use by the primary care provider. Three extensively used and tested instruments are described here.

The Nutrition Risk Index (NRI) was derived initially from questions used in the first National Health and Nutrition Examination Survey (NHANES I). Validity has been tested by the ability of the NRI to predict use of health services and correlations with a variety of anthropometric, laboratory, and clinical markers of nutritional status.

The DETERMINE instrument was developed as part of the Nutrition Screening Initiative - a 5-year campaign begun in 1990 to promote nutrition screening and better nutritional care among the elderly in the United States in response to the 1988 US Surgeon General's Workshop on Health Promotion and Aging. This instrument has been validated against measures of depressive symptoms and functional disability.



Probably the most extensively validated instrument is the Mini Nutritional Assessment (MNA). Validation criteria include nutritional status determined by physicians using standard anthropometric, clinical, and dietary measures mortality, and hospital cost.

These instruments all consist of 18 or fewer yes/no checklist items and involve a weighted score. Nutrition factors common to all three instruments include unintended weight loss, problems with chewing and swallowing, polypharmacy, and concurrent illness. The DETERMINE checklist and the MNA also include food access, social isolation, mobility, poverty, and intake of fruits, vegetables, and protein sources. The MNA includes questions to assess psychological problems, dementia, independent living status, and a self-assessment of nutrition problems and relative health status.”

The authors further reported: “In addition to assessing usual dietary behavior, providers are also encouraged to assess psychosocial factors that may mediate the effects of a counseling intervention. Such instruments have been developed primarily as evaluation measures in nutrition education intervention research. A mediator frequently used to guide counseling for a variety of health-related behaviors is Stage of Readiness to Change. This measure is used to determine the degree to which an individual is ready to begin counseling and how far he or she has advanced in the behavior change process. Several relatively brief and validated instruments assess stage of change for dietary fat intake; they can be implemented in the clinical setting.”

### **3. Intensive Multicomponent Behavioral Interventions**

Whitlock and colleagues presented a model for behavioral counseling interventions: “The Four A’s construct (ask, advise, assist, arrange) was originally developed by the National Cancer Institute to guide physician intervention in smoking cessation. Recently, the Canadian Task Force on Preventive Health Care proposed that clinicians use a Five A’s construct (adding an agree step) to organize their general approach to assisting patients with behavioral counseling issues (W. Elford, Canadian Task Force on Preventive Health Care, personal communication, December 2000). The U.S. Public Health Service used the A’s construct to report on high-quality, controlled clinical trials in tobacco cessation, many conducted in primary care settings to test brief, feasible, population level interventions. The A’s construct has also been applied to brief primary care interventions for a variety of other behaviors. To be congruent with the U.S. Public Health Service and Canadian Task Force concepts of the A’s construct, we adopted the following terminology to describe minimal contact interventions that are provided by a variety of clinical staff in primary care settings:

- **Assess:** Ask about/assess behavioral health risk(s) and factors affecting choice of behavior change goals/methods.
- **Advise:** Give clear, specific, and personalized behavior change advice, including information about personal health harms and benefits.
- **Agree:** Collaboratively select appropriate treatment goals and methods based on the patient's interest in and willingness to change the behavior.
- **Assist:** Using behavior change techniques (self-help and/or counseling), aid the patient in achieving agreed-upon goals by acquiring the skills, confidence, and social/environmental supports for behavior change, supplemented with adjunctive medical treatments when appropriate (e.g., pharmacotherapy for tobacco dependence, contraceptive drugs/devices).
- **Arrange:** Schedule follow-up contacts (in person or by telephone) to provide ongoing assistance/support and to adjust the treatment plan as needed, including referral to more intensive or specialized treatment."

LeBlanc and colleagues (2011) reported multicomponent interventions to include: "physical activity sessions, group sessions, individual sessions, technology-based intervention, specific weight-loss goals, spouse or family involvement, addressing barriers to weight loss, motivational assessment (for example, pros and cons of weight loss), selfmonitoring, incentives, or support after active intervention phase." An approach that incorporated multiple interventions that may be specifically tailored to individual beneficiaries would be appropriate.

## **Frequency of Visit**

For Medicare beneficiaries with obesity, who are competent and alert at the time that counseling is provided and whose counseling is furnished by a qualified primary care physician or other primary care practitioner and in a primary care setting, CMS covers high intensity behavioral counseling and therapy as follows:

- One face-to-face visit every week for the first month;
- One face-to-face visit every other week for months 2-6;
- One face-to-face visit every month for months 7-12, if the beneficiary meets the 3kg weight loss requirement as discussed below.

At the six month visit, a reassessment of obesity and a determination of the amount of weight loss must be performed. To be eligible for additional face-to-face visits occurring once a month for an additional six months, beneficiaries must have achieved a reduction in weight of at least 3kg over the course of the first six months of intensive therapy. This determination must be documented in the physician office records for applicable beneficiaries consistent with usual practice. For beneficiaries who do not achieve a weight loss of at least 3kg during the first six months of intensive therapy, a reassessment of their readiness to change and BMI is appropriate after an additional six month period.

McTigue and colleagues classified intensity “by using frequency of person-to-person contact in the first 3 months. Moderate intensity was defined as monthly contact, high intensity was defined as more frequent contact, and low intensity was defined as less frequent contact.” In a related systematic review on counseling to promote physical activity and a healthy diet, Lin and colleagues classified intensity by time as follows: “low [ $\leq 30$  minutes], medium [between 31 minutes and 6 hours of contact], or high [ $> 6$  hours of contact].” In a prior review on counseling to promote a healthy diet in adults, Pignone and colleagues rated intensity as follows: “Interventions with only one contact of 30 minutes or less were considered low intensity, those with six or more contacts of 30 minutes or more each were considered high intensity, and all others were considered medium intensity.”

## **Disparities**

Obesity is increasing in older adults in general. Zamboni and colleagues noted: “The prevalence of overweight and obesity is increasing among older age groups in developed countries, in both sexes, all ages, all races, all educational levels, both smokers and nonsmokers; an increase in BMI has been observed even among people with the highest levels of BMI” (Zamboni, 2005). In the general population, the USPSTF noted that “obesity is especially common in African Americans, some Hispanic populations, and Native Americans and some health sequelae reflect similar ethnic differences.” Thus, overall CMS encourages all beneficiaries with obesity to take advantage of this important benefit.

## **Summary**

As reported by the CDC, U.S. obesity rates have increased significantly over the past three decades and “obesity is now epidemic in the United States” (Kahn, 2009). In conjunction with the published literature, recommendations and professional guidelines, CMS thus believes that there is adequate evidence that intensive behavioral therapy for obesity is reasonable and necessary for the prevention or early detection of illness or disability, is appropriate for Medicare beneficiaries and has received a Grade B recommendation from the USPSTF.

## **IX. Conclusion**

The Centers for Medicare and Medicaid Services (CMS) has determined the following:

The evidence is adequate to conclude that intensive behavioral therapy for obesity, defined as a body mass index (BMI)  $\geq 30$  kg/m<sup>2</sup>, is reasonable and necessary for the prevention or early detection of illness or disability and is appropriate for individuals entitled to benefits under Part A or enrolled under Part B and is recommended with a grade of A or B by the U.S. Preventive Services Task Force (USPSTF).

Intensive behavioral therapy for obesity consists of the following:

1. Screening for obesity in adults using measurement of BMI calculated by dividing weight in kilograms by the square of height in meters (expressed in kg/m<sup>2</sup>);
2. Dietary (nutritional) assessment; and
3. Intensive behavioral counseling and behavioral therapy to promote sustained weight loss through high intensity interventions on diet and exercise.

The intensive behavioral counseling intervention for obesity should be consistent with the 5-A framework that has been highlighted by the USPSTF:

1. **Assess:** Ask about/assess behavioral health risk(s) and factors affecting choice of behavior change goals/methods.
2. **Advise:** Give clear, specific, and personalized behavior change advice, including information about personal health harms and benefits.
3. **Agree:** Collaboratively select appropriate treatment goals and methods based on the patient's interest in and willingness to change the behavior.
4. **Assist:** Using behavior change techniques (self-help and/or counseling), aid the patient in achieving agreed-upon goals by acquiring the skills, confidence, and social/environmental supports for behavior change, supplemented with adjunctive medical treatments when appropriate.
5. **Arrange:** Schedule follow-up contacts (in person or by telephone) to provide ongoing assistance/support and to adjust the treatment plan as needed, including referral to more intensive or specialized treatment.

For Medicare beneficiaries with obesity, who are competent and alert at the time that counseling is provided and whose counseling is furnished by a qualified primary care physician or other primary care practitioner and in a primary care setting, CMS covers:

- One face-to-face visit every week for the first month;
- One face-to-face visit every other week for months 2-6;
- One face-to-face visit every month for months 7-12, if the beneficiary meets the 3kg weight loss requirement as discussed below.

At the six month visit, a reassessment of obesity and a determination of the amount of weight loss must be performed. To be eligible for additional face-to-face visits occurring once a month for an additional six months, beneficiaries must have achieved a reduction in weight of at least 3kg over the course of the first six months of intensive therapy. This determination must be documented in the physician office records for applicable beneficiaries consistent with usual practice. For beneficiaries who do not achieve a weight loss of at least 3kg during the first six months of intensive therapy, a reassessment of their readiness to change and BMI is appropriate after an additional six month period.

For the purposes of this decision memorandum, a primary care setting is defined as one in which there is provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. Emergency departments, inpatient hospital settings, ambulatory surgical centers, independent diagnostic testing facilities, skilled nursing facilities, inpatient rehabilitation facilities and hospices are not considered primary care settings under this definition.

For the purposes of this decision memorandum a “primary care physician” and “primary care practitioner” will be defined consistent with existing sections of the Social Security Act (§1833(u)(6), §1833(x)(2)(A)(i)(I) and §1833(x)(2)(A)(i)(II)).

#### §1833(u)

(6) Physician Defined.—For purposes of this paragraph, the term “physician” means a physician described in section 1861(r)(1) and the term “primary care physician” means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

#### §1833(x)(2)(A)

Primary care practitioner—The term “primary care practitioner” means an individual—

(i) who—

(I) is a physician (as described in section 1861(r)(1)) who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; or

(II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1861(aa)(5)).

While this benefit is limited to primary care practitioners and primary care settings, it does not preclude primary care practitioners from screening beneficiaries for obesity and referring those who screen positive with a BMI  $\geq 30$  kg/m<sup>2</sup> to other practitioners and/or settings for intensive multicomponent counseling; however coverage remains only in the primary care setting.

## **Appendix A - Public Comment Citations**

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